

SEP 16 2008

2. 510(k) Summary**2.1 Submitter's Name and Address**

Argentis Biomedical Inc
11005 Indian Trail #102
Dallas, Texas 75229

Contact Person: Toni Miller PhD
LEC Associates LLC
26 Chestnut Ridge Rd #12
Montvale NJ 07645
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2.2 Date Prepared 12 September 2008

2.3 Device Name

Trade Name: ***SilverMed*™ Antimicrobial Hydrogel**

Common: Moist antimicrobial wound gel

Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and or Biologic

Regulatory Class: Unclassified

Product Code: FRO

2.4 Predicate Devices 807.92(a)(3)

***SilverMed*™ Antimicrobial Silver Hydrogel** is substantially equivalent to the following hydrogels:

- | | |
|---|---------|
| • Eutra Gel For Wound Dressing | K932291 |
| • SilvaSorb Silver Antimicrobial Wound Gel or
AcryDerm Silver Antimicrobial Wound Dressing | K011994 |
| • Silver Shield™ Antimicrobial Skin and
Wound Gel | K062212 |
| • Hydrolyzed Collagen Gel with Silver | K061227 |
| • Elta Silver Antimicrobial Wound Gel | K071703 |

2.5 Device Description

The Argentis **SilverMed™ Antimicrobial Hydrogel** is a moist hydrogel dressing designed to deliver antimicrobial silver that inhibits the growth of microbial contaminants. The high moisture content gel absorbs destructive components of wound exudate while promoting healthy tissue healing. Stabilizers prevent discoloration and staining from the dressing.

The product is available in 1.5 oz and 3 oz containers.

2.6 Assessment of Performance Data and Safety

SilverMed™ Antimicrobial Hydrogel is substantially equivalent to several silver hydrogel wound dressings: SilvaSorb Silver Antimicrobial Wound Gel/AKA AcryDerm Silver Antimicrobial Wound Dressing (K011994), Silver Shield™ Antimicrobial Skin and Wound Gel (K062212), Hydrolyzed Collagen Gel with Silver (K061227) and most recently Elta Silver Gel™ Advanced Ionic-Silver Wound Gel (K071703) and to Eutra Gel For Wound Dressing (K932291) except that this dressing does not contain antimicrobial silver.

SilverMed™ Antimicrobial Hydrogel has been subjected to *in vitro* and *in vivo* biocompatibility testing (ISO Modified Intracutaneous study, the ISO Intracutaneous Reactivity test and the ISO Delayed Hypersensitivity study) and cytotoxicity testing (ISO Agar Diffusion Diffusion (Direct)). These tests support the safe use of **SilverMed™ Antimicrobial Hydrogel** in contact with breached or compromised skin. *In vitro* Antimicrobial testing was assessed by the standard USP Antimicrobial Effectiveness Test <51>.

2.7 Statement of Intended Use

SilverMed™ Antimicrobial Hydrogel is indicated for the management of minor burns, superficial cuts, lacerations, abrasions and minor irritation of the skin. Under the supervision of a healthcare professional, it is indicated for partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, skin tears, grafted wounds, donor sites and surgical wounds.

These indications are identical or substantially equivalent to its predicates.

2.8 Technological Characteristics and Substantial Equivalence

SilverMed™ Antimicrobial Hydrogel is an amorphous gel wound filler that controls wound moisture levels through dual function of donation and absorption. Antimicrobial

action is conferred by its content of stabilized antimicrobial silver. The product carries the general classification name "Dressing, Wound and Burn, Hydrogel w/Drug and or Biologic". It is substantially identical to the predicate device Eutra Gel For Wound Dressing (K932291) in form and function except that its' preservative system has been replaced by antimicrobial silver technology. **SilverMed™ Antimicrobial Hydrogel** is substantially similar to the predicates SilvaSorb Silver Antimicrobial Wound Gel/AKA AcryDerm Silver Antimicrobial

Wound Gel (K011994), Silver Shield™ Antimicrobial Skin and Wound Gel (K062212), Hydrolyzed Collagen Gel with Silver (K061227) and Elta Silver Antimicrobial Wound Gel (K071703) in its active component of antimicrobial silver, in its hydrogel configuration and in its function.

The indications of use, technological properties and performance testing for **SilverMed™ Antimicrobial Hydrogel** are substantially equivalent to those of the predicate devices. The performance data testing exceeds the requirements as set forth by the USP. The biocompatibility testing and performance testing performed for the device also demonstrated that the device is safe and effective for the indications of use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2008

Argentis Biomedical Incorporated
% LEC Associates, LLC
Toni Miller, Ph.D.
President
26 Chestnut Ridge Road #12
Montvale, New Jersey 07645

Re: K073019

Trade/Device Name: SilverMed Antimicrobial Hydrogel
Regulation Number: Unclassified
Product Code: FRO
Dated: August 17, 2008
Received: October 14, 2008

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

1. Indications for Use Statement

Device Name: SilverMed Antimicrobial Hydrogel**Indications for use:**

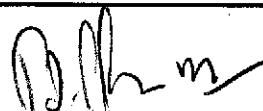
SilverMed™ Antimicrobial Hydrogel is indicated for the management of minor burns, superficial cuts, lacerations, abrasions and minor irritation of the skin. Under the supervision of a healthcare professional, it is indicated for partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, skin tears, grafted wounds, donor sites and surgical wounds.

Prescription Use X
(Part 21 CFR 801 Subpart D)

And/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)


(Division Sign-Off)
Division of General, Restorative, and
Neurological Devices

510(k) Number K073019
Concurrence of CDRH, Office of Device Evaluation (ODE)